

Applicants: Paz Einat et al.  
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Remarks

Claims 1-22 are pending and under examination in the subject application. Applicants have also added new claims 23-26.

Applicants have hereinabove amended claims 4, 6, and 8, and added new claims 23-26. Applicants maintain that the amendments to claims 4, 6, and 8, and new claims 23-26 raise no issue of new matter. Support for the amendments to claims 4 and 8 and new claims 23 and 25 can be found in the specification as originally filed at, *inter alia*, page 5, line 20 to page 6, line 6; page 14, lines 3-5; page 15, line 29 to page 16, line 6; and claims 4 and 8. Support for the amendments to claim 6 can be found in the specification as originally filed at, *inter alia*, page 16, lines 7-11; and claim 6. Support for new claims 24 and 26 can be found in the specification as originally filed at, *inter alia*, page 5, lines 12-19; and page 14, line 9. Accordingly, applicants respectfully request entry of this Amendment. Upon entry of this Amendment claims 1-26 will be pending and under examination.

Restriction Requirement

In the April 19, 2005 Office Action, the Examiner required restriction to one of the following allegedly independent and distinct inventions characterized by the following Groups I-VIII:

- I. Claims 3 and 5 drawn to a method for treatment of an apoptosis-related disease comprising administering an antibody against a WWP1 polypeptide;
- II. Claims 4 and 5 drawn to a method for treatment of an apoptosis-related disease comprising administering an antisense against a WWP1 polypeptide;

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III. Claims 7 and 9, drawn to a method of potentiating a chemotherapeutic treatment of an apoptosis-related disease comprising administering an antibody against a human WWP1 polypeptide with a chemotherapeutic agent;

IV. Claims 8 and 9, drawn to a method of potentiating a chemotherapeutic treatment of an apoptosis-related disease comprising administering an antisense fragment targeted to human WWP1 with a chemotherapeutic agent;

V. Claims 10-11, drawn to an antisense oligonucleotide capable of inhibiting the expression of WWP1 polypeptide;

VI. Claims 12, 14 and 16, drawn to a process for determining the WWP1 polypeptide levels in cells of subjects;

VII. Claims 13, 15 and 17, drawn to a process for determining levels of polynucleotide encoding WWP1 in a subject; and

VII. Claims 18-22, drawn to a process for obtaining a compound which modulates or promotes apoptosis in a cell.

On pages 3-4 of the April 19, 2005 Office Action, the Examiner alleged that the inventions of Groups I-IV are unrelated. The Examiner alleged that in the instant case the different methods are not useful together because they have materially different modes of operation with different effects.

On page 4 of the April 19, 2005 Office Action, the Examiner alleged that searching any of inventions of Groups I-IV together would impose a serious search burden.

On page 5 of the April 19, 2005 Office Action, the Examiner alleged that the inventions of Groups I, III, and V are unrelated. The Examiner alleged that in the instant case the

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different inventions are not useful together because they have materially different modes of operation with different effects. The Examiner further alleged that because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other it would be a burden to search these inventions in a single application.

On pages 5-6 of the April 19, 2005 Office Action, the Examiner alleged that the inventions of Groups II and V are related as product and process of use. The Examiner alleged that in the instant case the different inventions are not useful together because they have materially different modes of operation with different effects. The Examiner further alleged that because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other it would be a burden to search these inventions in a single application.

On page 6 of the April 19, 2005 Office Action, the Examiner alleged that the inventions of Groups IV and V are related as product and process of use. The Examiner alleged that in the instant case the different inventions are not useful together because they have materially different modes of operation with different effects. The Examiner further alleged that because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other it would be a burden to search these inventions in a single application.

On pages 6-7 of the April 19, 2005 Office Action, the Examiner alleged that the inventions of Groups I-IV and VI are unrelated. The Examiner alleged that in the instant case the different methods are not useful together because they have materially different modes of operation with different effects. The Examiner further alleged that because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other it would be a burden to search these

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inventions in a single application.

On page 7 of the April 19, 2005 Office Action, the Examiner alleged that the inventions of Groups I-IV and VII are unrelated. The Examiner alleged that in the instant case the different methods are not useful together because they have materially different modes of operation with different effects. The Examiner further alleged that because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other it would be a burden to search these inventions in a single application.

On page 8 of the April 19, 2005 Office Action, the Examiner alleged that the inventions of Groups I-IV and VIII are unrelated. The Examiner alleged that in the instant case the different methods are not useful together because they have materially different modes of operation with different effects. The Examiner further alleged that because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other it would be a burden to search these inventions in a single application.

On pages 8-9 of the April 19, 2005 Office Action, the Examiner alleged that the inventions of Groups V and VI are unrelated. The Examiner alleged that in the instant case the different methods are not useful together because they have materially different modes of operation with different effects. The Examiner further alleged that because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other it would be a burden to search these inventions in a single application.

On page 9 of the April 19, 2005 Office Action, the Examiner alleged that the inventions of Groups V and VII are unrelated. The Examiner alleged that in the instant case the different

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methods are not useful together because they have materially different modes of operation with different effects. The Examiner further alleged that because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other it would be a burden to search these inventions in a single application.

On pages 10-11 of the April 19, 2005 Office Action, the Examiner alleged that the inventions of Groups VI, VII and VIII are unrelated. The Examiner alleged that in the instant case the processes are unrelated as they comprise distinct steps and utilize different products which demonstrate that each method has a different mode of operation. The Examiner further alleged that because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other it would be a burden to search these inventions in a single application.

On page 11 of the April 19, 2005 Office Action, the Examiner alleged that claim 1 links the inventions of Group I-IV, and claims 2 and 6 link the inventions of Groups III and IV. The Examiner further alleged that the restriction requirement between the linked inventions is subject to nonallowance of the linking claims. The Examiner also alleged that upon allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application.

In response, applicants hereby elect, with traverse, the invention of the claims 1, 2, 5, 6, 9, 23, and 24 drawn to a method of treatment of an apoptosis related disease in a subject comprising administering an siRNA.

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Applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement. Under 35 U.S.C. §121, restriction may be required if two or more independent and distinct inventions are claimed in one application.

Under M.P.E.P. §802.01, "independent" means there is no disclosed relationship between the subjects disclosed. The inventions of Groups I-II are both drawn to methods of treating an apoptosis-related disease in a subject by administering an inhibitor of the WWP1 polypeptide. Groups III-IV are drawn to methods of potentiating a chemotherapeutic treatment of an apoptosis related disease using inhibitors of the WWP1 polypeptide. Group V is drawn to inhibitors of the WWP1 polypeptide. Groups VI and VII are drawn to processes for determining levels of the WWP1 polypeptide or the polynucleotide encoding the WWP1 polypeptide. Groups VIII is drawn to processes for obtaining compounds that modulate or promote apoptosis in either a cell expressing the WWP1 polypeptide or measuring their effect on the activity of the WWP1 polypeptide. Applicants therefore maintain that the claims of Groups I-VIII are not independent.

Furthermore, under MPEP §803, there are two criteria for a proper restriction requirement: 1) the invention must be independent or distinct (discussed above), and 2) there must be a serious burden on the Examiner if restriction is required. MPEP §803 unambiguously provides that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent and distinct inventions." Applicants respectfully submit that there would not be a serious burden on the Examiner if restriction is not required between Groups I-VIII. A search for prior art material to the patentability of the claims 1, 2, 5, 6, 9, 23, and 24 drawn to a method of treatment for an apoptosis-related disease in a subject comprising administering an siRNA, would necessarily turn up prior art

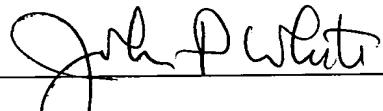
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material to the patentability of the claims of Groups I-VIII. Any search for treating an apoptosis-related disease using an inhibitor of the WWP1 polypeptide will turn up other inhibitors of the WWP1 polypeptide, other methods of treatment, and methods of using the WWP1 polypeptides. Since there is no burden on the Examiner to examine the elected claims 1, 2, 5, 6, 9, 23, and 24 Groups I-VIII together in the subject application, it is therefore resubmitted that Groups I-VIII should be examined on the merits.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

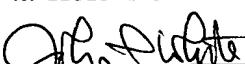
No fee, other than the fee of \$60.00 for a one-month extension of time and the fee of \$100.00 for extra claims which are enclosed in a check for \$160.00, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

 6/17/05

John P. White	Date
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